

7-18-95

EFFICACY REVIEW

DATE: IN 3-23-94 OUT 1-18-95

FILE OR REG. NO. 37425-GO

PETITION OR EXP. PERMIT NO. \_\_\_\_\_

DATE DIV. RECEIVED January 10, 1994

DATE OF SUBMISSION January 7, 1994

DATE SUBMISSION ACCEPTED \_\_\_\_\_

TYPE PRODUCT(S): (I,)D, H, F, N, R, S \_\_\_\_\_

DATA ACCESSION NO(S) . 431305-01, -02, -03, -04, -05, -06 & 431611-01;  
D200835; S457204; Case# 040783; AC:165

PRODUCT MGR. NO. 13-LaRocca/Heyward

PRODUCT NAME(S) Durasect Long-acting Livestock Pour-On

COMPANY NAME SmithKline Beecham Animal Health

SUBMISSION PURPOSE Provide performance data in support of claims  
for control of horn fly, face fly & stable fly  
on beef & dairy cattle and calves with pour-on.

CHEMICAL & FORMULATION Permethrin [(3)-phenoxyphenyl)methyl (+)-cis,  
trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate]\*  
\* cis/trans ratio: 1.0%  
Maximum 35% (+) cis, (8.1 lbs./gal. ready-to-use pourable liquid)  
minimum 65% (+) trans

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession  
(MRID) Number 431305-01, having been obtained from standard field  
testing conducted according to § 95-8(a)(1)-(4) & (5)(viii) on pp.  
255-6 and § 95-8(a)(7) & (8) on p. 258 and meeting the standard of  
§ 95-8(b)(1)(ii)(B) and the standard of § 95-8(b)(1)(iv), both on  
p. 259 of the Product Performance Guidelines, are adequate to sup-  
port the claims for control of horn fly and face fly on dairy cat-  
tle and calves in California when the subject product is applied  
according to label rates and directions. Similarly, the data pre-  
sented in MRID No. 431305-02, having been similarly obtained from  
a similarly conducted field test meeting the same standard, are  
adequate to support the horn fly control claim on beef cattle in  
Texas when similarly applied. Also, data in MRID No. 431305-03  
from similar testing meeting the same requirements and standard are  
adequate to support the horn fly control claim on beef cattle and  
calves in Arkansas when similarly applied, and data in MRID No.  
431305-04 from Missouri are adequate to support claims for horn fly  
and face fly control on beef cattle in that state. (continued)

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Data in MRID No. 431305-05 from Oklahoma are adequate to support the horn fly claim on beef cattle and calves in that state. Data in MRID No. 431305-06 from Maryland are marginally adequate to support both horn and face fly control on cattle of unspecified type and additionally to support a claim for reduction but not control of stable fly based on the standard of § 95-8(b)(1)(iii), subpart (A). Since face fly control met the previously mentioned standard while horn fly control barely failed to meet it for both treatments, this is considered adequate confirmation of results observed against these pests in other states; however, seasonal reduction of stable fly barely exceeded the 50% level, which is not sufficient to support the control claim. Furthermore, since this is the only stable fly data provided, the label claim must be reduced to aid in control until such time as additional data demonstrating satisfactory stable fly control is submitted. Data in MRID No. 431611-01, having been obtained from a standard field test meeting the same requirements but failing to meet the standard due to the presence of considerable pyrethroid resistance as documented by the calculated resistance ratio of 250 to fenvalerate presented statistically, does nevertheless demonstrate substantial reduction of horn fly under difficult conditions on beef cattle in Georgia.

The data in MRID Nos. 431305-01, -04 and -06 are adequate to support the label claim "Controls Face Flies for at Least 1 Month" when the subject product is applied according to label rates and directions. However, none of the data in all 7 MRID Nos. presenting horn fly control data are adequate to support the label claim "Controls Horn Flies for 2 to 3 Months" due to either failure of 90% reduction in infestation to be maintained for the required length of time, 8 to 12 weeks, or failure of the testing and observations to be continued for that length of time. We will accept a label claim "Controls Horn Flies for Up to 2 Months" in place of the proposed label claim. As previously mentioned, we will accept a claim for aids in control of stable fly.

RL Vern L. McFarland, IRB